REMARKS

Claims 1-3, 5-12 and 21-24 were examined. Applicants amend claims 1 and 22 and submit additional claim 25. Applicants submit that no new matter is added herein as the amendments and additional claims are supported at least by paragraphs [0051]-[0053], FIGs. 4-5 and FIG. 9 of the application. Hence, Applicants respectfully request reconsideration of claims 1-3, 5-12 and 21-24; and consideration of additional claim 25.

The Patent Office rejects claims 1-3, 6 and 8 under 35 U.S.C. §102(b) and claims 5, 7, 9, 10-12 and 21-24 under 35 U.S.C. §103(a). Reconsideration of the pending claims is respectfully requested in view of the above amendment and the following remarks.

A. 35 U.S.C. §102(b): Rejection of Claims 1-3, 6 & 8

The Patent Office rejects claims 1-3, 6 and 8 under 35 U.S.C. §102(b) and (e) as anticipated by U.S. Patent No. 6,162,202 by Sicurelli (Sicurelli), US Patent No. 4,411,657 by Galindo (Galindo), and US Patent No 6,283,951 by Flaherty (Flaherty).

Claims 1-3, 6 and 8 describe a system for detecting tissue contact and penetration depth comprising a needle with a first opening to a lumen of the needle and a second opening to the same lumen of the needle, the needle having the lumen extending between the first opening and the second opening, and the second opening including at least one aperture in the needle to the lumen located at a predetermined distance from the first opening. The system also includes a fluid measurement assembly coupled with a portion of the needle to measure no significant change in pressure as compared to a first pressure of a fluid dispensed in the needle, a second pressure that is a significant increase in pressure as compared to the first pressure when the needle contacts tissue and the first opening becomes occluded, and a third pressure that is a significant increase in pressure as compared to the second pressure when the needle penetrates tissue and an aperture of a second opening in the needle becomes occluded.

In the ***Response to Arguments*** section of the current Office Action the Patent Office admits that the prior art does not explicitly disclose using a device to measure the third pressure, as claimed, but that the claims are anticipated because it would be inherent that the devices could

be employed in various situations such as ones in which the pressure changes resulting from an aperture becoming occluded.

Applicant disagrees with the Patent Office's assertion because it is not necessary to measure the pressure resulting from employment of the references in untaught situations. As noted below and by the Patent Office, none of the references teach an aperture becoming occluded. Thus, the teachings of the reference are satisfied without the capability of reading pressures greater than those expected in the taught situations. Moreover, there is no need to compare pressure readings to thresholds greater than those expected in the taught situations. For example, the references can detect an infusion problem by measuring an infusion pressure that exceeds a threshold indicating that flow is partially or mostly occluded, without the expense of measuring and comparing a much higher pressure resulting from complete occlusion of one or both openings of a needle (e.g., as required by the claims).

Thus, it is not necessary for a pressure measurement assembly of any of the references to be capable of measuring or detecting a significant increase in pressure from a pressure of a fluid dispensed in the needle to a the pressure when a first of two opening in the needle becomes occluded. Certainly, there is no necessity for a pressure measurement assembly of any of the references to be capable of measuring or detecting a significant increase in pressure from when a first of the two openings becomes occluded to when both openings become occluded. Moreover, none of the references conceives, enables or makes necessary indicating to an operator that the needle has contacted tissue or penetrated tissue as required; or that the operator should proceed with advancement, proceed with advancement slowly, or stop advancement, as required by new claim 25.

More specifically, Claims 1-3, 6 and 8 are not anticipated by Sicurelli for at least the reason that Sicurelli does not disclose a pressure measurement assembly configured to measure a second pressure that is a significant increase in pressure as compared to the first pressure when the first opening becomes occluded, and a third pressure that is a significant increase in pressure as compared to the second pressure when an aperture of a second opening located a predetermined distance from the first opening becomes occluded, as required by claim 1. Sicurelli describes a flexible irrigation syringe tip made of a bendable material such as silicone or propylene to flush a canal such as a tooth canal (see Abstract and column 2, lines 42-67). To this end, the flexible syringe needle may communicating with pressure sensor 550 for

controlling the flow pressure of the fluid discharged from the flexible syringe needle during flushing of the canal to safely avoid excess pressure (see column 5, lines 39-51 and 59-67). Sicurelli teaches flushing using openings in the side but not in the tip of the flexible syringe (see FIG. 4). Consequently, Sicurelli does not teach or enable measuring a second pressure that is a significant increase in pressure as compared to the first pressure when the first opening becomes occluded, and a third pressure that is a significant increase in pressure as compared to the second pressure when an aperture of a second opening located a predetermined distance from the first opening becomes occluded, as required by claim 1.

Also, claim 1-3, 6 and 8 are not anticipated by Galindo for at least the reason that Galindo does not disclose a pressure measurement assembly configured to measure a second pressure that is a significant increase in pressure as compared to the first pressure when the first opening becomes occluded, and a third pressure that is a significant increase in pressure as compared to the second pressure when an aperture of a second opening located a predetermined distance from the first opening becomes occluded, as required in claim 1. Galindo teaches a hypodermic needle having openings in the perimeter of the needle and having a pinpoint tip without a tip opening, so that the tip can separate nerve fascicles without cutting them (see abstract and Figs. 1-6). Glanido describes fluid pressures of injection when the tip is located inside the muscle, the perineural space and the nerve (see column 2, lines 43-50 and FIG. 8). However, Galindo doesn't teach a distinction between pressure or pressure changes as the openings of the needle become occluded. Hence, Galindo does not teach or enable measuring a second pressure that is a significant increase in pressure as compared to the first pressure when the first opening becomes occluded, and a third pressure that is a significant increase in pressure as compared to the second pressure when an aperture of a second opening located a predetermined distance from the first opening becomes occluded, as required by claim 1.

Next, claims 1-3, 6 and 8 are not anticipated by Flaherty for at least the reason that Flaherty does not teach or enable a pressure measurement assembly configured to measure a second pressure that is a significant increase in pressure as compared to the first pressure when the first opening becomes occluded, and a third pressure that is a significant increase in pressure as compared to the second pressure when an aperture of a second opening located a predetermined distance from the first opening becomes occluded. Flaherty teaches a transvascular system for delivering drug to tissue of a blood vessel using needle: (a) 64 having

openings 75 when distal tip 64 of the needle has closed tip 73, or (b) having a single opening 74 in distal tip 64 of the needle (see Abstract; column 10, lines 59-67; and FIG. 5C). In addition, the system of Flaherty may include a pressure sensor provided on needle assembly 62 and/or the drug delivery element to continuously monitor pressure at or near the delivery site; and/or a flow measurement sensor, allowing the amount of drug being delivered to the selected tissue region to be precisely measured (see paragraph [0017] lines 42-52). However, Flaherty does not describe measuring pressure or flow when an aperture of a second opening in the needle becomes occluded. Consequently, Flaherty does not teach or enable the aperture of a second opening becoming occluded, or measuring a second pressure that is a significant increase in pressure as compared to the first pressure when the first opening becomes occluded, and a third pressure that is a significant increase in pressure as compared to the second pressure when an aperture of a second opening located a predetermined distance from the first opening becomes occluded, as required by claim 1.

Hence, Applicant respectfully requests that the Patent Office withdraw the rejection of claims 1-3, 6 and 8 under 35 U.S.C. §102(b).

B. 35 U.S.C. §103(a): Rejection of Claims 5, 7, 9 & 10

The Patent Office rejects claims 5, 7, 9 and 10 under 35 U.S.C. §103(a) as obvious over Sicurelli or Galindo or Flaherty in view of Sicurelli or Galindo or Flaherty. Claims 5, 7, 9 and 10 depend from claim 1 and therefore contain all the limitations of that claim. For at least the reasons stated above, claims 5, 7, 9 and 10 are not obvious over Sicurelli or Galindo or Flaherty in view of Sicurelli or Galindo or Flaherty. An argument analogous to the one above for claim 1 applies to show that none of these references teach the above noted limitations of claim 1. Consequently, the combination of these references also does not teach the above noted limitations of claim 1.

In addition, by having a first opening to a lumen and a second opening to the lumen of the needle, where the second opening includes at least one aperture to the lumen located at a predetermined distance from the first opening, and a fluid pressure measurement assembly able to measure no significant change in pressure, a significant increase in pressure as compared to a first pressure, and a significant increase in pressure as compared to a second pressure, embodiments described in the specification, for example, without limitation thereto, provide

numerous unexpected benefits such as: (1) allowing it to be detected when the needle contacts a cavity or vessel wall; (2) allowing it to be detected when the needed has been inserted a predetermined depth into the cavity or vessel wall, such as where the predetermined depth is the distance between the first hole and the second hole (see at least paragraphs [0004]-[0006], [0030]-[0032] and [0035] of the Application; and Figures 1-3B); and (3) notifying an operator to proceed with advancement of the needle, proceed with advancement of the needle slowly, or stop advancement of the needle, depending on the detection of a change in pressure as noted above (see at least paragraphs [0051]-[0053] and FIGs. 4, 5, and 9 of the application; claim 23 and additional claim 25). However, none of the references teach or enable such benefits.

In addition, Applicant traverses that given the cited references, the distance of the aperture from the end of the needle would have been an obvious matter of design choice for at least the reason that Applicant has pointed out unexpected benefits above that provide example advantages and purposes to solve stated problems that are not addressed by simply controlling the amount of flow, as taught by the references. Specifically, the references do not contemplate, make necessary, or enable measuring a second pressure that is a significant increase in pressure as compared to a flow pressure, when the first opening becomes occluded; and measuring a significant increase in pressure as compared to the second pressure, when the second aperture of a needle becomes occluded. Thus, a practitioner would not find such a design choice obvious without relying solely upon Applicants claims. Hence, Applicant respectfully requests that the Patent Office come up with a reference in support of this position in accordance with MPEP § 2144.03. Thus, Applicant respectfully requests that the Patent Office withdraw the rejection to claims 5, 7, 9 and 10 under 35 U.S.C. §103(a).

C. 35 U.S.C. §103(a): Rejection of Claims 11, 12 and 21-24

The Patent Office rejects claims 11, 12 and 21-24 under 35 U.S.C. §103(a) as obvious over Sicurelli or Galindo or Flaherty in view of Sicurelli or Galindo or Flaherty in view of U.S. Patent No. 5,662,107 of Sakariassen (Sakariassen). Sakariasssen is cited for disclosing a computer processor coupled to a fluid pressure assembly, but does not teach or enable the above note limitations of claim 1.

Claims 11, 12 and 21-24 depend from claim 1 and therefore contain all the limitations of that claim. For at least the reason stated above for claim 1, claims 11, 12 and 21-24 are not

obvious over the cited references. Applicant respectfully requests that the Patent Office withdraw the rejection to claims 11, 12 and 21-24 under 35 U.S.C. §103(a).

In addition to being dependent upon allowable base claims, Applicants disagree with the rejection of dependent claims 11, 12, and 21-24 for at least the reason that none of the references teach a computer processor, signal processor, circuit, visual indicator, or audible feedback system able to determine rate of changes in pressure, penetration depths of the needle, or to make indications based on measuring significant increases in pressure as compared to a first pressure and a second pressure, as required by those claims.

Hence, for at least the additional reasons noted above, Applicants respectfully request the Patent office withdraw the rejection of dependent claims 11, 12 and 21-24.

D. Additional Claim 25

Applicants submit additional claim 25 is patentable over the cited references for at least the reasons described above in support of its base claim, as well as the additional limitations of claim 25.

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,
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CERTIFICATE OF TRANSMISSION
I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

Jessica Huester 06/10/09
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